

MARYLAND REGISTER

Proposed Action on Regulations

Transmittal Sheet PROPOSED OR REPROPOSED Actions on Regulations	Date Filed with AELR Committee	TO BE COMPLETED BY DSD
	12/02/2011	Date Filed with Division of State Documents
		Document Number
		Date of Publication in MD Register

1. Desired date of publication in Maryland Register: 1/13/2012

2. COMAR Codification

Title Subtitle Chapter Regulation

10 12 01 01-.20

3. Name of Promulgating Authority

Department of Health and Mental Hygiene

4. Name of Regulations Coordinator

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X- New Regulations

: Md. R
(vol.) (issue) (page nos) (date)

7. Is there emergency text which is identical to this proposal:

8. Incorporation by Reference

9. Public Body - Open Meeting

OPTIONAL - If promulgating authority is a public body, check to include a paragraph that final action will be considered at an open meeting.

☐ Check if the system should send a copy of the proposal to the Children's Environmental Health and Protection Advisory Council.

I certify that the attached document is in compliance with the Administrative Procedure Act. I also certify that the attached text has been approved for legality by Kathleen A. Ellis, Assistant Attorney General, (telephone #410-767-1867) on November 17, 2011. A written copy of the approval is on file at this agency.

Joshua M. Sharfstein, M.D.

December 2, 2011

410-767-6500

Title 10
DEPARTMENT OF HEALTH AND MENTAL HYGIENE
Subtitle 12 ADULT HEALTH
10.12.01 Surgical Abortion Facilities

Authority: Health General Article, §20-209, Annotated Code of Maryland

Notice of Proposed Action

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The Secretary of Health and Mental Hygiene proposes to adopt new Regulations .01—.20 under a new chapter COMAR 10.12.01 Surgical Abortion Facilities.

Statement of Purpose

The purpose of this action is to regulate surgical abortion sites. The Department's authority to regulate surgical abortion sites is set forth in Health General Article, §20-209, Annotated Code of Maryland. The law both limits the State's authority to interfere with the decision of a woman to terminate a pregnancy, and provides that the State may adopt regulations that:

- a) Are both necessary and the least intrusive method to protect the life or health of the woman; and
- b) Are not inconsistent with established medical practice.

Sites to be included in these regulations are outpatient facilities that perform surgical abortions as a regular service, except if otherwise licensed and regulated by the Department.

Surgical abortions, as with other medical procedures, must be performed by a licensed physician and are subject to State regulation through the Board of Physicians. The proposed regulations of surgical abortion facilities will supplement State regulation of licensed physicians and other health professionals.

Most abortions are performed safely and without complication. Most sites providing surgical abortions in Maryland are accredited for quality by a national nonprofit accrediting body. The Department proposes these regulations to strengthen quality and safety assurances of surgical abortion facilities and to allow the Department to act in the instance of a violation of the standard of care for surgical abortions.

The proposed regulations address deficiencies identified in recent Maryland cases. A review of the Board of Physicians public orders from 1991 revealed five physicians were disciplined for violating the standards of care governing abortions. According to the disciplinary records, women died or were seriously injured in each case. Women were harmed by improper administration or monitoring of general anesthesia under the care of three of the five physicians. In addition to those disciplinary actions, in August and

September, 2010, the Board directed charging documents to three additional physicians for performing abortions in a manner inconsistent with standards of practice at a site in Elkton, Maryland.

These proposed regulations will provide protections and address deficiencies identified in these cases. For instance, these regulations establish surgical abortion facility requirements for professional credentialing, facility administration, administration of anesthesia, emergency services, quality assurance, inspection and sanctions including suspension of site license for non-compliance.

These proposed regulations were developed through a deliberative and inclusive process. The Department researched laws of other states as well as public records of the Maryland Board of Physicians. Clinical experts in the fields of gynecology, anesthesiology, obstetrics, and outpatient surgery were consulted. Department staff met with advocacy groups with a wide range of views. Draft regulations were posted on the Department's website for public comment from July 29, 2011 through August 19, 2011. Approximately 69 comments were received. The Department is grateful to those who contributed their comment throughout the development of these regulations. All comments were closely examined.

The following is a summary of the substantive categories of comment received during this public comment period and the Department's assessment and decision.

SCOPE OF CHAPTER.

Comment: The regulations should apply to all locations where surgical abortions are performed regardless of frequency.

Response: The regulations cover facilities where surgical abortions are performed as a regular service on a routine basis. The regulations do not cover other medical offices where a surgical abortion may occasionally be performed as an infrequent but medically necessary element of patient care within a medical practice of internal or family medicine, obstetrics and gynecology or other practice. The reason is that physicians generally may perform procedures that are medically necessary but rare as part of their professional practice.

Comment: Why not require surgical abortion facilities to conform to all of the Ambulatory Surgical Center (ASC) regulations?

Response: Most surgical abortion sites do not meet the formal definition of an ambulatory surgical center and thus cannot be incorporated into those existing regulations. However, these proposed regulations are based on the framework of the ASC regulations and provide appropriate safety standards, modified in specific areas where the nature and circumstances of surgical abortion procedures differ from other procedures.

Comment: Why regulate abortions and not other kinds of surgical procedures, for example plastic surgery, which may be performed in sites that are not licensed by the Department?

Response: The Maryland law authorizing these regulations applies specifically to

abortion procedures. The Department will consider requesting authority for other types of facilities as circumstances warrant.

RADIOLOGY.

Comment: Radiologic services, and specifically sonography, were not addressed or required.

Response: Regulation .12 Laboratory Services was changed to add "and Radiologic" in title and within text of the regulation. The decision as to what radiological services are necessary to be performed is a matter to be determined by the facility's physician or physicians.

SCOPE OF SUSPENSION.

Comment: If a facility's license for abortion is suspended by the State, must the entire facility close?

Response: Regulation .17D(2) added "surgical abortion" to define the services specifically suspended if a surgical facility license were suspended. Generally speaking, unrelated services would not have to be suspended.

CONFIDENTIALITY.

Comment: The regulations need to strengthen patient confidentiality protections.

Response: The following new regulations were added:

- Regulation .04 Inspections by the Department requires the Department to keep patient information confidential in accordance with State and federal laws.
- Regulation .13 Medical Records requires the facility to transfer a patient's record with a patient's consent, except to the extent that information in a record is necessary for a patient's care in an emergency transfer.
- Regulation .04 Inspections by the Department was added to expressly require Department staff to be held to the requirements for medical review committees as described in Health Occupations Article, §1-401, Annotated Code of Maryland.

PENALTIES.

Comment: The penalties for violations should be increased.

Response: Regulation .19 Penalties was amended to allow the Secretary to impose an administrative penalty of up to \$1,000 for a violation of any provision of this chapter.

ANESTHESIA.

Comment: Requirements for anesthesia should be the same as requirements in the Ambulatory Surgical Center (ASC) regulations.

Response: Regulation .08A Anesthesia Services was amended to reflect language that expands the original ASC regulation to include categories of anesthesia/sedation. This section was also modified as to who could administer anesthesia. Regulation .08B was added to address "if more than an unsupplemented local anesthetic is needed to accomplish a surgical procedure:

- (1) There shall be a pre-anesthesia evaluation performed by one of the individuals listed in §A of this regulation; and
- (2) The anesthetic risk to the patient shall be documented in the patient's medical

record.”

FEES.

Comment: Why are there no fees for a surgical abortion license?

Response: Fees were inadvertently omitted from the draft regulations. Regulation .03 adds an application and renewal fee.

The Department anticipates that this new chapter will become effective July 1, 2012.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

I. Summary of Economic Impact.

These new regulations require an applicant to submit to the Department a nonrefundable fee of \$1,500 for an initial license and a nonrefundable fee of \$1,500 every 3 years thereafter for a license renewal. In addition, a licensee may be assessed an administrative penalty of up to \$1,000 for a violation of any provision of this chapter.

II. Types of Economic Impact.

	Revenue (R+/R-)	
	Expenditure (E+/E-)	Magnitude
A. On issuing agency:	(R+)	\$19,500 every 3 years
B. On other State agencies:	NONE	
C. On local governments:	NONE	
	Benefit (+) Cost (-)	Magnitude
D. On regulated industries or trade groups:	(-)	\$19,500 every 3 years
E. On other industries or trade groups:	NONE	
F. Direct and indirect effects on public:	NONE	

III. Assumptions. (Identified by Impact Letter and Number from Section II.)

A. The Department anticipates approximately 13 facilities to apply for an initial license within the first year. (13 x \$1,500 = \$19,500) In addition, administrative penalties may be assessed; however, this impact cannot be quantified because it is unknown how many violations will occur.

D. See II.A. above

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Michele A. Phinney, Director, Office of Regulation and Policy Coordination, Department of Health and Mental Hygiene, 201 West Preston Street, Room 512, Baltimore, MD 21201, or call 410-767-6499; TTY:800-735-2258, or email to regs@dnhmh.state.md.us, or fax to 410-767-6483. Comments will be accepted through February 13, 2012. A public hearing has not been scheduled.

Economic Impact Statement Part C

A. Fiscal Year in which regulations will become effective: FY 2013

B. Does the budget for the fiscal year in which regulations become effective contain funds to implement the regulations?

Yes

C. If 'yes', state whether general, special (exact name), or federal funds will be used: Budgetary provision to implement these regulations will be included in the Department's FY 2013 request. (General funds)

D. If 'no', identify the source(s) of funds necessary for implementation of these regulations:

E. If these regulations have no economic impact under Part A, indicate reason briefly:

F. If these regulations have minimal or no economic impact on small businesses under Part B, indicate the reason and attach small business worksheet.

The three year \$1,500 licensure fee will have minimal impact on the affected clinics. The fee can be absorbed by the affected clinics as an essential element of their business operations and funded through their existing revenue stream. The fee will not impede operations at the clinics, many of which have elected to be accredited by a national organization at a substantially higher fee.

G. Small Business Worksheet:

Attached Document:

Title 10

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 12 ADULT HEALTH

10.12.01 Surgical Abortion Facilities

Authority: Health General Article, §20-209, Annotated Code of Maryland

BEGIN NEW

.01 Definitions.

- A. In this chapter, the following terms have the meanings indicated.
- B. Terms Defined.
 - (1) "Department" means the Department of Health and Mental Hygiene.
 - (2) "Facility" means a surgical abortion facility.
 - (3) Health Professional.
 - (a) "Health professional" means an individual who is licensed, certified, or otherwise authorized under Health Occupations Article, Annotated Code of Maryland, to provide health care services.
 - (b) "Health professional" does not include a physician.
 - (4) "Physician" means an individual licensed to practice medicine in this State under Health Occupations Article, Title 14, Annotated Code of Maryland.
 - (5) "Regular service" means that surgical abortion procedures are performed onsite on a routine basis.
 - (6) "Surgical abortion facility" means an outpatient facility that provides surgical termination of pregnancy as a regular service except if the facility is regulated by the Department under:
 - (a) Health General Article, Title 19, Subtitle 2, Annotated Code of Maryland;
 - (b) Health General Article, Title 19, Subtitle 3A, Annotated Code of Maryland; or
 - (c) Health General Article, Title 19, Subtitle 3B.01 (B), Annotated Code of Maryland.

.02 License Required.

- A. A person may not establish or operate a surgical abortion facility without obtaining a license from the Secretary.
- B. License Period. A license is valid for 3 years from the date of issuance, unless suspended or revoked by the Secretary.
- C. A license issued under this chapter is not transferable.

.03 Licensing Procedures.

- A. A person desiring to operate a facility shall:
 - (1) Be in compliance with all applicable federal and State laws and regulations;
 - (2) File an application as required and provided by the Department; and
 - (3) Submit a written description of its quality assurance program as required by Regulation .16 of this chapter.
- B. In addition to meeting all of the requirements of Regulation .03A and F of this chapter, the applicant or licensee shall submit a nonrefundable fee of \$1,500 with an application for:
 - (1) An initial license; or
 - (2) A license renewal.
- C. Based on information provided to the Department by the applicant and the Department's own investigation, the Secretary shall:
 - (1) Approve the application unconditionally;
 - (2) Approve the application conditionally; or
 - (3) Deny the application if the applicant:
 - (a) Has been found liable for or has been convicted of:
 - (i) Fraud or a felony that relates to Medicaid or Medicare, or
 - (ii) A crime involving moral turpitude; or
 - (b) Does not comply with the requirements of this chapter.
- D. Denial of License for Prior Revocation or Consent to Surrender License.
 - (1) The Secretary may deny a license to:
 - (a) A corporate applicant if the corporate entity has an owner, director, or officer:
 - (i) Whose conduct caused the revocation of a prior license, or
 - (ii) Who held the same or similar position in another corporate entity which had its license revoked; or
 - (b) An individual applicant:
 - (i) Whose conduct caused the revocation of a prior license, or

(ii) Who held a position as owner, director, or officer in a corporate entity which had its license revoked; or
(c) An individual or corporate applicant that has consented to surrender a license as a result of a license revocation action.

(2) The Secretary shall also consider the factors identified in Regulation .19B of this chapter when deciding whether to deny a license.

E. A person aggrieved by a decision of the Secretary under this regulation may appeal the Secretary's action by filing a request for a hearing in accordance with Regulation .20 of this chapter.

F. Renewal of License.

(1) At least 60 days before a license expires, the licensee shall submit to the Secretary:

(a) A renewal application; and

(b) The fee as specified in §B of this regulation.

(2) The Secretary shall renew the license for an additional 3-year period for a licensee that meets the requirements of this chapter.

.04 Inspections by the Department.

A. Open for Inspection. A licensed facility or an entity proposing to operate such a facility shall be open during normal business hours, or any other times that the facility is serving patients, for inspection by the Department and by any other agency designated by the Department to:

(1) Verify compliance with this chapter; and

(2) Investigate a complaint concerning patient care and safety as described in §B of this chapter.

B. Complaints.

(1) In response to a complaint, the Department may:

(a) Require the facility to perform and submit its own investigation; or

(b) In its discretion, conduct an on-site investigation of a complaint.

(2) In order to determine whether an on-site investigation as described in §B(1)(b) of this regulation is appropriate, the factors the Department shall consider include, but are not limited to:

(a) Whether the complainant has first-hand knowledge of the alleged incident;

(b) The facility's regulatory history, including the number of verified prior complaints;

(c) Whether the Department has recently inspected the facility, and whether the incident would have been observed during the prior review;

(d) The nature of the complaint, including degree of potential serious harm to patients.

(3) If the complaint concerns the performance of a physician, health professional, or standards of practice, the Department shall refer the complaint to the board that licenses, certifies, or otherwise authorizes the physician or health professional to provide services under the Health Occupations Article, Annotated Code of Maryland.

(4) The Department shall:

(a) Comply with the requirements for medical review committees as described in Health Occupations Article, §1-401, Annotated Code of Maryland; and

(b) Keep patient information confidential in accordance with State and federal laws.

C. Noncompliance. If the Department determines that a facility fails to meet any provision of this chapter, the Department shall:

(1) Advise the facility of the exact nature of the violation; and

(2) Require that the facility specify what corrective action it is taking and monitor the facility to ensure that it takes corrective action.

D. Records and Reports. The facility shall make its records and reports available to the Department onsite at the facility during an inspection.

.05 Administration.

A. Administrator.

(1) Each facility shall have an administrator, who is responsible for the daily operation of the facility, including but not limited to:

(a) Consulting with the staff to develop and implement the facility's policies and procedures in accordance with §C of this regulation;

(b) Organizing and coordinating the administrative functions of the facility;

(c) Coordinating the provision of services that the facility provides;

(d) Training the staff on the facility's policies and procedures, and with applicable federal, State, and local laws and regulations; and

(e) Ensuring that all personnel:

(i) Receive orientation and have experience sufficient to demonstrate competency to perform assigned patient care duties, including proper infection control practices;

(ii) Are licensed or certified by an appropriate occupational licensing board to practice in this State, if required by law; and

(iii) Perform or delegate duties and responsibilities in accordance with standards of practice as defined by the Health Occupations Article, Annotated Code of Maryland.

- (2) The administrator shall ensure that:
 - (a) The facility's policies and procedures as described in §C of this regulation are:
 - (i) Reviewed by staff at least annually and are revised as necessary; and
 - (ii) Available at all times for staff inspection and reference; and
 - (b) All appropriate personnel implement all policies and procedures as adopted.
- B. Medical Director.
 - (1) The surgical abortion facility shall have a medical director who:
 - (a) Is responsible for the overall medical care that is provided by the facility;
 - (b) Advises and consults with the staff of the facility on all medical issues relating to services provided by the facility.
 - (c) Shall develop protocols for the management of surgical patients and emergency situations.
 - (2) The medical director shall ensure that the protocols referenced in §B(1)(c) of this regulation are:
 - (a) Available on site at all times for reference; and
 - (b) Reviewed annually and revised as necessary.
 - (3) The medical director shall be a physician licensed to practice in Maryland.
- C. Policies and Procedures. The facility shall have policies and procedures concerning the following:
 - (1) The scope and delivery of services provided by the facility either directly or through contractual arrangements;
 - (2) Personnel practices, including but not limited to:
 - (a) Procedures for the accountability of personnel involved in patient care;
 - (b) Job descriptions on file for all personnel; and
 - (c) Procedures to ensure personnel are free from communicable diseases.
 - (3) Postoperative recovery, if applicable;
 - (4) The transfer or referral of patients who require services that are not provided by the facility;
 - (5) Infection control for patients and staff;
 - (6) Pertinent safety practices, including the control of fire and mechanical hazards;
 - (7) Preventive maintenance for equipment to ensure proper operation and safety; and
 - (8) The services and procedures specified in Regulations .07—.12 of this chapter.

.06 Personnel.

A. Qualifications of Physicians and Staff. A facility shall ensure that all physicians and other health professionals who are employees or contractual staff have been appropriately trained and licensed or certified under the Health Occupations Article, Annotated Code of Maryland.

B. Credentialing of Physicians. The facility shall collect, review, and document the following information concerning a physician licensed under the Health Occupations Article, Title 14, Annotated Code of Maryland:

- (1) The physician's education;
- (2) The professional experience of the physician, including:
 - (a) Any board certification or specialty training of the physician, and
 - (b) Any post-graduate training;
- (3) Any license or registration to practice a health occupation ever held by the physician, including DEA registration;
- (4) Any hospital where the physician was appointed or employed during the last 10 years, including:
 - (a) The name of the hospital,
 - (b) The term of appointment or employment, and
 - (c) Privileges held and any disciplinary action taken, including suspension, revocation, limitation, or voluntary surrender;
- (5) The physician's professional liability insurance for the last 5 years, including:
 - (a) The physician's present carrier;
 - (b) The physician's current limits of coverage;
 - (c) The physician's current types of coverage, and
 - (d) Restrictions on the physician's coverage;
- (6) Any claim that has been made against the physician in the practice of a health occupation in the last 5 years, and the status of the claim;
- (7) Any physical or mental condition that currently impairs the physician's ability to exercise privileges;
- (8) Any complaint or report, permitted to be disclosed by law, which has been filed with any state licensing or disciplinary body, or comparable body of the armed forces; and
- (9) Data provided by the National Practitioner Data Bank.

C. For a physician who has privileges in a licensed Maryland hospital, the administrator may verify, through the hospital, the credentials described in §B of this regulation.

D. The administrator shall establish a procedure for the biennial reappointment of a physician which includes:

- (1) An update of the information required in §B of this regulation; and
- (2) An assessment of the physician's performance pattern based on an analysis of:

- (a) Complaints filed with the facility,
 - (b) Malpractice claims filed,
 - (c) Utilization, quality, and risk data,
 - (d) Adherence to policies, bylaws, and procedures, and
 - (e) Physician practice patterns as reviewed through the facility's quality assurance program.
- E. Credentialing of Health Professionals.
 - (1) Direct Hires.
 - (a) The facility shall collect, review, and verify evidence of the following information for all licensed or certified health professionals that are employed by the facility:
 - (i) A current license or certificate to practice in this State; and
 - (ii) Malpractice insurance, if required by the facility.
 - (b) The administrator shall approve the delineation of services to be provided by the health professional.
 - (2) Non-direct Hires. When a licensed physician uses a health professional to provide services at the facility, and that person is not employed by the facility, the licensed physician who employs the health professional is responsible for verifying the information required in §E(1) of this regulation.

.07 Surgical Abortion Services.

- A. Surgical abortion procedures shall be performed in a safe manner by a physician credentialed by the facility under Regulation .06.
- B. An administrator shall develop and implement policies, procedures, and protocols for the provision of surgical abortion services including but not limited to:
 - (1) Personnel;
 - (2) Pre-operative testing and examinations;
 - (3) Surgical procedures;
 - (4) Post-anesthesia care and observation;
 - (5) Discharge planning;
 - (6) Emergency services;
 - (7) Informed consent; and
 - (8) Safety.
- C. Before conducting a surgical procedure, a physician or other qualified health professional shall conduct a history and physical examination.
- D. If the assessments required by §C of this regulation are performed before the day of surgery, on the day of surgery a physician or qualified health professional shall reassess and document on the patient's medical record any change in the patient's clinical status that could have an effect on the surgical procedure to be performed and the anesthesia to be used.
- E. Discharge. Before discharge from the facility, the patient shall be evaluated by a physician or an appropriately trained health professional. This evaluation shall be documented in the patient's record.

.08 Anesthesia Services.

- A. Anesthetics, including moderate sedation, deep sedation, or general anesthesia shall be administered by:
 - (1) A physician qualified to administer anesthesia; or
 - (2) A certified registered nurse anesthetist in accordance with:
 - (a) Health Occupations Article, §8-205, Annotated Code of Maryland; and
 - (b) COMAR 10.27.06.
- B. If more than an unsupplemented local anesthetic is needed to accomplish a surgical procedure:
 - (1) There shall be a pre-anesthesia evaluation performed by one of the individuals listed in §A of this regulation; and
 - (2) The anesthetic risk to the patient shall be documented in the patient's medical record.

.09 Emergency Services.

- A. Basic Life Support. Licensed personnel employed by the facility shall have certification in basic life support. A licensed staff individual trained in basic life support shall be on duty whenever there is a patient in the facility.
- B. The facility shall have:
 - (1) A registered nurse available on site for emergency treatment whenever there is a patient in the facility; and
 - (2) At least one physician available by phone 24 hours a day to respond to emergency situations; and
- C. When sedation or general anesthesia is administered, the facility shall have at least the following emergency equipment available to the procedure rooms:
 - (1) Oxygen;
 - (2) Mechanical ventilatory assistance including airways and manual breathing bag;
 - (3) Automated external defibrillator (AED);
 - (4) Equipment to monitor blood pressure, pulse, and oxygen levels;
 - (5) Suction equipment; and
 - (6) Emergency medical equipment and supplies specified by the medical staff.

D. When general anesthesia is administered, a facility shall have available in the procedure room:

- (1) Laryngoscopes;
- (2) Endotracheal tubes; and
- (3) Cardiac monitoring equipment.

.10 Hospitalization.

A. The surgical abortion facility shall have an effective procedure for the transfer of patients to a nearby hospital when care beyond the capabilities of the facility is required.

B. Procedures for emergency transfer to a hospital shall include, at a minimum:

- (1) Written protocols and procedures related to emergency transfer procedures;
- (2) A mechanism for notifying the hospital of a pending emergency case;
- (3) A mechanism for arranging appropriate transportation to the hospital;
- (4) Protocols for transmitting a copy of the patient's medical record to the hospital; and
- (5) Appropriate training for staff in the facility's written protocols and procedures.

.11 Pharmaceutical Services.

A. The surgical abortion facility shall:

- (1) Provide drugs under the direction of an authorized prescriber; and
- (2) Develop and implement policies and procedures for pharmacy services in accordance with accepted professional practice.

B. Administration of Drugs.

- (1) Staff shall prepare and administer drugs according to established policies and acceptable standards of practice.
- (2) Staff shall report adverse drug reactions to the licensee's medical director or physician.
- (3) Orders given orally for drugs shall be followed by a written order which is signed by the authorized prescriber.

.12 Laboratory and Radiologic Services.

A. The administrator shall develop and implement policies and procedures for obtaining routine and emergency laboratory and radiological services to meet the needs of the patient. Policies and procedures shall include:

- (1) Turn-around time;
- (2) Review of laboratory reports; and
- (3) Documentation of laboratory results.

B. Laboratory facilities shall be:

- (1) Approved under the Clinical Laboratory Improvement Act (CLIA); and
- (2) Licensed by the State under COMAR 10.10.03.

C. The facility shall include in the patient's medical records:

- (1) Laboratory reports; and
- (2) Radiological findings.

.13 Medical Records.

A. The facility shall maintain a complete, comprehensive, and accurate medical record for a patient.

B. A patient's medical record shall include at least the following:

- (1) Patient identifier;
- (2) Significant medical history and results of a physical examination;
- (3) Documentation of care or services provided;
- (4) Evidence of consent; and
- (5) Discharge diagnosis.

C. The facility shall:

- (1) Send a copy of the medical record with the patient on:
 - (a) Referral to another physician or other licensed health professional; or
 - (b) Transfer to a hospital;

(2) Except to the extent that information in a record is necessary for a patient's care in an emergency transfer, transfer a patient's record only with a patient's consent;

- (3) If appropriate, use the medical record when instructing the patient and the family; and

(4) Comply with all disclosure requirements as set forth in Health-General Article, Title 4, Subtitle 3, Annotated Code of Maryland.

.14 Patients' Rights and Responsibilities

The administrator shall ensure that the facility develops and implements written policies and procedures concerning patients' rights and responsibilities, including but not limited to:

A. The opportunity to participate in planning their medical treatment; and

B. Confidentiality of medical records and the right to approve or refuse release of records to any individual outside the facility, except as provided by federal or State law.

.15 Physical Environment.

A. The administrator shall ensure that the facility has a safe, functional, and sanitary environment for the provision of surgical services.

B. A procedure room shall be designed and equipped to ensure that surgical abortion procedures conducted can be performed in a manner that ensures the safety of all individuals in the area.

C. The facility shall have a separate recovery room and waiting area.

D. The facility shall meet the requirements for handling, treatment, and disposal of special medical wastes as provided in COMAR 10.06.06.

.16 Quality Assurance Program.

A. The administrator shall ensure that the facility develops and maintains a quality assurance program which includes:

(1) Monitoring and evaluation of the quality of patient care; and

(2) Identification, evaluation, and resolution of care problems.

B. The facility shall conduct ongoing quality assurance activities and document the activities on a continuous basis, but not less than quarterly.

C. The administrator shall ensure that the facility develops a quality control procedure to monitor and document the safety and performance of all biomedical equipment.

D. The facility shall document the following information for all quality assurance activities:

(1) A description of identified problems;

(2) Findings;

(3) Conclusions;

(4) Recommendations;

(5) Actions taken;

(6) Results; and

(7) Follow-up.

.17 Emergency Suspension.

A. The Secretary may immediately suspend a license on a finding that the public health, safety, or welfare requires emergency action.

B. The Department shall deliver a written notice to the licensee:

(1) Informing the licensee of the emergency suspension;

(2) Giving the reasons for the action and the regulation or regulations with which the licensee has failed to comply that forms the basis for the emergency suspension; and

(3) Notifying the licensee of the licensee's right to request a hearing and to be represented by counsel.

C. The filing of a hearing request does not stay the emergency action.

D. When a license is immediately suspended, the licensee shall:

(1) Immediately return the license to the Department; and

(2) Stop providing surgical abortion procedures immediately.

E. A person aggrieved by the action of the Secretary under this regulation may appeal the Secretary's action by filing a request for a hearing in accordance with Regulation .20 of this chapter.

F. Hearing.

(1) The Office on Administrative Hearings shall:

(a) Conduct a hearing as set forth in Regulation .20 of this chapter; and

(b) Issue a proposed decision within 10 business days of the close of the hearing record.

(2) Exceptions may be filed by an aggrieved person pursuant to COMAR 10.01.03.

G. Final Decision.

(1) The Secretary shall make a final decision in accordance with COMAR 10.01.03.

(2) If the Secretary's final decision does not uphold the emergency suspension, the licensee may resume operation.

.18 Revocation of License.

A. The Secretary, for cause shown, shall notify the licensee of the Secretary's decision to revoke the facility's license. The revocation shall be stayed if a hearing is requested.

B. The Secretary may revoke a license if the licensee:

(1) Has been convicted of:

(a) Fraud or a felony that relates to Medicaid or Medicare, or

(b) A crime involving moral turpitude; or

(2) Does not comply with the requirements of this chapter.

C. The Secretary shall consider the factors identified in Regulation .19B of this chapter when deciding whether to revoke a license.

D. The Secretary shall notify the licensee in writing of the following:

(1) The effective date of the revocation;

- (2) The reason for the revocation;
 - (3) The regulations with which the licensee has failed to comply that form the basis for the revocation;
 - (4) That the licensee is entitled to a hearing if requested, and to be represented by counsel;
 - (5) That the facility shall stop providing services on the effective date of the revocation if the licensee does not request a hearing;
 - (6) That the revocation shall be stayed if a hearing is requested; and
 - (7) That the licensee is required to surrender the license to the Department if the revocation is upheld.
- E. A person aggrieved by the action of the Secretary under this regulation may appeal the Secretary's action by filing a request for a hearing in accordance with Regulation .20 of this chapter.

.19 Penalties.

- A. Administrative Penalty. The Secretary may impose an administrative penalty of up to \$1,000 for a violation of any provision of this chapter.
- B. When considering whether to impose an administrative penalty and the amount of the penalty, the Secretary shall consider the following factors:
- (1) The number, nature, and seriousness of the violation or violations;
 - (2) The extent to which the violation or violations are part of an ongoing pattern during the preceding 24 months;
 - (3) The degree of risk, caused by the violation or violations, to the health, life, or safety of the patients of the facility;
 - (4) The efforts made by, and the ability of, the licensee to correct the violation or violations in a timely manner; and
 - (5) Such other factors as justice may require.
- C. A person aggrieved by the action of the Secretary under §A of this regulation may appeal the Secretary's action by filing a request for a hearing in accordance with Regulation .20 of this chapter.

.20 Hearings.

- A. A request for a hearing shall be filed with the Office of Administrative Hearings, with a copy to the Office of Health Care Quality of the Department, not later than 30 days after receipt of notice of the Secretary's action. The request shall include a copy of the Secretary's action.
- B. A hearing requested under this chapter shall be conducted in accordance with:
- (1) State Government Article, §10-201—10-227, Annotated Code of Maryland;
 - (2) COMAR 28.02.01; and
 - (3) COMAR 10.01.03.
- C. The burden of proof is as set forth in COMAR 10.01.03.28.
- D. Unless otherwise stated in this chapter, the Office of Administrative Hearings shall issue a proposed decision within the time frames set forth in COMAR 28.02.01.
- E. The aggrieved person may file exceptions as set forth in COMAR 10.01.03.35.
- F. The Secretary shall issued a final decision in accordance with COMAR 10.01.03.35.

END NEW

JOSHUA M SHARFSTEIN, M.D.

Secretary of Health and Mental Hygiene